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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,832	09/28/1999	KEIKO YUGAWA	43888-067	1982

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/406,832	<b>Applicant(s)</b> YUGAWA ET AL.	
	<b>Examiner</b> ALEX NOGUEROLA	<b>Art Unit</b> 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 21 April 2003.

2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 5-83 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 5-20, 22-37, 39-54 and 56-82 is/are allowed.

6) ☒ Claim(s) 21, 38, 55 and 83 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 28 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All    b) ☐ Some \*    c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Response to Amendment***

1. Applicant's amendment of April 21, 2003 does not render the application allowable.

***Response to Arguments***

2. Applicant's arguments filed April 21, 2003 have been fully considered but they are not persuasive. With respect to the rejections of claims 21 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Heisei 10-227755 in view of the CAPLUS abstract of Maslinska-Solich, Applicant has submitted a declaration alleging, "[t]he listing of maleic acid or anhydride as an example of a hydrophilic macromolecule is not correct and one skilled in this art would recognize that the listing of maleic acid or anhydride as a hydrophilic macromolecule in a reaction layer is in error." The examiner has not been persuaded that the teaching of maleic acid or its anhydride in Heisei 10-227755 is in error. First, the declaration is merely Declarant's opinion of how one with ordinary skill in the art would construe the disclosure, and opinion declarations, unlike factual declarations, cannot be dispositive of the issue in question. Second, maleic acid or anhydride is not the only compound in paragraph [0007] of Heisei 10-227755, acrylic acid and metaacrylic acid, for example, are also listed. Third, no certificate of correction, or equivalent patent correction document, has been provided for Heisei 10-227755 that replaces monomers or compounds in paragraph [0007] with the corresponding polymers. Last, even assuming maleic acid or its anhydride is an accidental disclosure, there is precedent that an

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accidental disclosure can constitute an accidental teaching. See, for example, *General Electric Company v. Watson, Comr. Pats.* 127 USPQ 326, 329.

***Status of Objections and Rejections Pending Since the Office Action of December 19, 2002***

3. The objection to claim 38 is withdrawn.

4. The rejection of claims 20, 21, 37, 38, and 54-81 under 35 U.S.C. § 112, first paragraph is withdrawn.

5. The rejections of claims 21 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Heisei 10-227755 in view of CAPLUS abstract of Maslinska-Solich are withdrawn.

6. The rejection of claims 55 and 59-63 under 35 U.S.C. § 103(a) as being unpatentable over Crismore et al. in view of Vetter et al. and Gotoh et al. is withdrawn.

*Claim Rejections - 35 USC § 103*

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 21, 38, 55, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over English language translation of Heisei 10-227755 in view of the newly cited Aoyama et al. (US 5,424,204).

Addressing claims 21, 38, and 55, Heisei 10-227755 discloses a method for stabilizing glucose dehydrogenase for use in a glucose sensor ([Means of solution] and second sentence in paragraph [0007]) comprising an electrically insulating base plate, an electrode system including a working electrode and a counter electrode formed on the base plate (Figure 1), and a reaction layer which is formed in contact or in the vicinity of the electrode system (Figure 2), wherein the reaction layer contains glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone and at least one additive is added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone ([Means of solution] and paragraph [0007]). Heisei 10-227755 also discloses a list of additives (paragraph [0007]) that includes maleic acid, which is in the Markush group of additives in Applicant's claim. It would have been obvious to one with ordinary skill in the art at the time the invention was made to choose maleic acid or a maleate from among the list of additives disclosed by Heisei 10-227755 in order to optimize the glucose sensor. Although, carboxymethyl cellulose showed the best performance (paragraph [0007]), this was for limited

tests, such as an aqueous glucose solution ([Embodiment Example 1]). Heisei 10-227755 contemplates a variety of samples, such as blood, urine, or food products (paragraph [0013]). One with ordinary skill in the art would select the additive best suited for the sample from the disclosed list of additives. Furthermore, as shown by Aoyama et al. maleic acid was a known stabilizer for glucose dehydrogenase (the abstract and col. 3, ll. 30-36). So, it would have been obvious to one with ordinary skill in the art at the time the invention was made to use maleic acid as an additive as taught by Aoyama et al. in the invention of Heisei 10-227755 because as taught by Aoyama et al. maleic acid will also stabilize the glucose dehydrogenase.

Addressing claim 83, a preserved linear response as claimed is not mentioned by Heisei 10-227755 in view of the newly cited Aoyama et al.; however, since the structure of the biosensor and the composition of the reagent layer in Heisei 10-227755 as modified by Aoyama et al. are the same as claimed by Applicant, the properties of the biosensors should be the same.

*Allowable Subject Matter*

9. Claims 5-20, 22-37, 39-54, and 56-82 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:
- a) Claims 5, 22, and 39: the prior art of record does not teach phthalic acid or phthalate in a reaction layer with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline;
  - b) Claims 6-20 depend directly or indirectly from allowable Claim 5;
  - c) Claims 23-36 depend directly or indirectly from allowable Claim 22;
  - d) Claims 40-53 depend directly or indirectly from allowable Claim 39;
  - e) Claim 82 requires that glucose sensor of claim 55 further comprises "at least one stabilizer selected from the group consisting of a metal salt, an organic acid, a protein, and a sugar and a derivative thereof." Heisei 10-227755 as modified by Aoyama et al. teach using maleic acid as a stabilizer. Providing an additional stabilizer from the claimed group of stabilizers is not disclosed by these references;
  - f) Claims 56-63 depend directly or indirectly from allowable Claim 82;
  - g) Claims 64 and 73 each require a stabilizer and a buffer to be added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone, wherein the stabilizer and the buffer are selected from limited groups of compounds. Heisei 10-227755 as modified by Aoyama et al. teach using maleic acid as a stabilizer. There is no disclosure of a stabilizer and buffer as claimed being added glucose dehydrogenase whose coenzyme is pyrrolo-quinoline quinone;
  - h) Claims 65-72 depend directly or indirectly from allowable Claim 64; and
  - i) Claims 74-81 depend directly or indirectly from allowable Claim 73.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

*Alex Noguera*  
Alex Noguera  
May 7, 2003